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10/725,574

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EXAMINER

HAND, MELANIE JO

ART UNIT

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3761

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/725,574 | Applicant(s) SIGURJONSSON ET AL. | |
| | Examiner MELANIE J. HAND | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14-16, 18-20 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14-16, 18-20, 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 19, 2009 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 12, 14-16, 18-20 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims. However examiner will address the essence of applicant's arguments herein. With respect to applicant's argument that Lawry does not disclose a proximal surface of the second facing layer 16 that is coplanar with the proximal surface of the backing layer, in light of the amendment to the specification filed January 19, 2009, such arguments are persuasive and no new matter rejection will be made. Lawry does not teach or suggest this newly added limitation.

3. With respect to arguments regarding whether gauze defines through-extending apertures, it appears that applicant intends for those recited through-extending apertures to be linear apertures. While gauze does not define a grid of linear straight through-extending apertures, it is possible to trace a path from an aperture on the body-facing surface of the gauze to the backing layer. Thus the gauze of Lawry defines a grid of through-extending apertures, even though their paths may be tortuous. Examiner's interpretation of "grid pattern" differs from applicant. While a grid itself is a series of horizontal and vertical lines, a grid pattern consist of

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elements that may define or lie along horizontal lines, and thus is a broader concept than a simple grid, as those elements may be identically sized or may not, and may be arranged differently but still aligned along said horizontal and vertical lines. Upon further review conducted of applicant's specification, it is noted that only receptacles 18 in the absorbent core are arranged in a grid-like pattern, not the apertures in the second skin facing layer beneath the core. The specification in fact explicitly states that the apertures of the second skin facing layer are formed randomly. Thus a rejection under 35 U.S.C. 112 is made in this action.

4. With respect to arguments regarding the gauze impregnated with gel disclosed by Lawry and whether such a layer then has nonapertured sections that consist of silicone gel, this argument is persuasive. However, after said further review of the specification, neither the term "non-apertured section" nor "consists" is found anywhere in the specification. Thus, applicant lacks sufficient support for this limitation.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis for the following: (1) non-apertured sections of the second facing layer, (2) nonapertured sections that consist of silicone hydrophobic gel, (3) apertures in the second facing layer that are arranged in a grid pattern, all recited in independent claims 12 and 24.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 12, 14-16, 18-20 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With regard to independent claims 12 and 24, there is no support in the disclosure as originally filed for a second facing layer defining a grid pattern of through-extending apertures arranged across the second facing layer. The specification as originally filed specifically discloses random formation of apertures and the only grid pattern disclosed is a "grid-like" pattern of receptacles, which are present in the core and are not through extending apertures in the second facing layer.

8. Claims 12, 14-16, 18-20 and 24-28 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because, with regard to independent claims 12 and 24, there is no support for non-apertured sections of the second facing layer that consist of gel. The disclosure as originally filed makes mention of skin treatment agents, for example, blended into the silicone elastomer. Thus, the agents will be present in the gel and in fact must be present in some physical form in the gel of the second facing layer that allows them to impart their benefit to the user. Thus the nonapertured sections, which are defined by the layer structure, may contain other elements, which examiner interprets as supporting open ended "comprising" claim language, rather than at least one embodiment where the second layer and the nonapertured sections therein specifically consist of only gel.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 12, 14-16, 18, 20, 24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steer et al (GB 2061732 A) in view of any one of Argenta (U.S. Patent No. 5,636,643), Lockwood (U.S. Patent Application Publication No. 2002/0161346) and Henley (U.S. Patent No. 6,458,109), each one individually, and further in view of Lawry (U.S. Patent Application Publication No. 2002/0156410).

With respect to **claim 12**: Steer discloses a wound dressing having opposed outermost backside and bodyside surfaces. The bodyside surface is generally planar (Fig. 1) and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface. The dressing comprises the following: an absorbent core in the form of foam layer 13 defining opposed proximal and distal surfaces, the distal surface including a central

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portion and a border portion (Figs. 1,4, Page 1, lines 39-43); a liquid impervious, vapor permeable backing layer E defining opposed proximal and distal surfaces (Fig. 1, Page 2, lines 55-58), a central portion of the proximal surface of the backing layer E extending over the distal surface of the absorbent core 13 (Fig. 1), and the backing layer E defining a border portion extending beyond and surrounding peripheral edges of the absorbent core (Fig. 1), the distal surface of the backing layer defining the backside surface of the wound dressing; a first skin adherent facing layer in the form of a layer of adhesive on the bottom/proximal surface directly secured to the proximal surface of the border portion of the backing layer E and surrounding the peripheral edges of the absorbent core (Page 2, lines 61-63), a proximal surface of the first facing layer defining a portion of the bodyside surface of the wound dressing inasmuch as the proximal surface of the first facing layer is not obscured from attaching to the skin by layers 11,13 and D (Figs. 2,4); and a second facing layer 11 directly bonded to and coextensive with the proximal surface of the absorbent core 13, a proximal surface of the second facing layer 11 defining a portion of the bodyside surface of the wound dressing and necessarily being coplanar with the proximal surface of the border portion of the backing layer E carrying the first facing layer, inasmuch as the border portion extends in all directions around the periphery of the second facing layer 11 and core 13 to attach to the skin to keep the dressing together. (Page 2, lines 58-63) A periphery of the second facing layer 11 is also necessarily contiguous with a periphery of the first facing layer since the adhesion of the first facing layer to the skin holds the dressing together, which is interpreted herein as a tight seal around the core and second layer 11 such that they do not shift relative to one another. The second facing layer 11 defines a grid pattern of through extending apertures 20 arranged across the second facing layer 11 and non-apertured regions surrounding the apertures (Fig. 1, Page 1, lines 34-36, 47-51); wherein the bodyside surface of the wound dressing necessarily consists of the proximal surfaces of the first

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and second facing layers as they are the only surfaces that adhere to the skin when the bandage is in use. The second facing layer 11 is composed of a skin adherent hydrophobic gel compound, the thickness of the non-apertured regions consisting of the gel compound inasmuch as the layer consists only of the gel compound. (Page 1, lines 64-79)

Steer discloses that the extending portion of layer E holds the dressing in place and discloses that the layer E is an adhesive tape, i.e. the first facing layer is attached to the entirety of the layer not just the border or extending portion. However, bandage outer covers/backing sheets/surgical drapes covering bandages to secure them in place at a wound site with adhesive tape present only at a border portion that extends beyond the periphery of the dressing core are well known in the art as supported by Argenta ('643, Fig. 1, Col. 6, lines 32-40), Lockwood ('346, Fig. 39, ¶0118) and Henley ('109, Abstract) and serve as an alternate equally effective configuration of the adhesive layer compared to the layer disclosed by Steer covering the entire proximal surface of the backing layer E. Thus, it would be obvious to one of ordinary skill in the art to modify the article of Steer such that the first facing layer of adhesive is secured only to the border portion of the backing layer with a reasonable expectation of success to provide an equally effective way of securing the bandage in place.

Thus it would be obvious to one of ordinary skill in the art to modify the article of Steer by replacing the layer E with a surgical drape with a first skin adherent facing layer in the form of a layer of adhesive directly secured only to the proximal surface of the border portion of the backing layer and surrounding the peripheral edges of the absorbent core with a reasonable expectation of success to maintain the layer's ability to hold the dressing together.

Steer discloses several skin adherent gel compounds including those using silicone as a binder, but does not explicitly disclose that the second facing layer is composed of a skin adherent hydrophobic silicone gel compound. Lawry discloses a wound dressing having a

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second facing layer 16 composed of a skin adherent hydrophobic silicone gel compound. ('410, ¶¶0037,0038) The article of Lawry seeks to solve a similar problem in the art to that with which applicant is concerned. Further, the silicone gel is equally or more capable of adhering to the skin compared to the hydrophilic gels disclosed by Steer because hydrophobic gels won't absorb sweat causing the gel to break down. Thus it would be obvious to one of ordinary skill in the art to modify the article of Steer by replacing the water soluble hydrocolloid of the second facing layer with a hydrophobic silicone gel as disclosed by Lawry to ensure the second facing layer is still capable of adhering to the skin and will not absorb sweat, thus preventing breakdown of the layer during wear.

With respect to **claim 14**: The border portion of the backing layer E of Steer is substantially parallel with the distal surface of the absorbent core. (Fig. 1)

With respect to **claim 15**: The border portion of the backing layer E includes at least two opposed elongate sections, each opposed elongate section extending from a corresponding side of the absorbent core. (Fig. 2)

With respect to **claim 16**: The first facing layer present on the border portion of layer E in the article suggested by Steer as modified by Lawry is a pressure sensitive adhesive. (Page 2, lines 59-61)

With respect to **claim 18**: The first facing layer is sufficiently porous so as not to occlude moisture transmission through the backing layer.

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With respect to **claim 19**: The first facing layer of the article suggested by Steer and modified by Lawry contains materials for the first facing layer (pressure-sensitive adhesive) and second facing layer (hydrophobic gel) that are identical to materials claimed for the recited first and second facing layers. Thus while Steer does not explicitly disclose adherence properties for the first facing layer and Lawry does not disclose adherence properties of the second facing layer it would be obvious to one of ordinary skill in the art to modify the article suggested by Steer and modified by Lawry such that the first facing layer has greater skin adherence properties than the second facing layer.

With respect to **claim 20**: Steer does not disclose that the peripheral edges of the absorbent core have a bevel extending downwardly and inwardly towards a central axis thereof from the distal surface to the proximal surface thereof. Lawry discloses in Fig. 4 an absorbent core 14 wherein the peripheral edges of the absorbent core have a bevel extending downwardly and inwardly towards a central axis thereof from the distal surface to the proximal surface thereof. Since Lawry discloses that both the unbeveled core in Fig. 2, substantially identical structurally and functionally to the core of Steer, and the beveled core in Fig. 4 are equally effective for providing a dressing for burn wounds, it would be obvious to one of ordinary skill in the art to modify the dressing of Steer such that the peripheral edges of the absorbent core have a bevel extending downwardly and inwardly towards a central axis thereof from the distal surface to the proximal surface thereof.

With respect to **claim 24**: Steer discloses a wound dressing having opposed outermost backside and bodyside surfaces. The bodyside surface is generally planar (Fig. 1) and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent

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a wound surface. The dressing comprises the following: a polymeric-foam-based absorbent core in the form of polymeric foam layer 13 defining opposed proximal and distal surfaces, the distal surface including a central portion and a border portion (Figs. 1,4, Page 1, lines 39-43); a liquid impervious, vapor permeable backing layer E defining opposed proximal and distal surfaces (Fig. 1, Page 2, lines 55-58), the backing layer defining a central portion wherein the proximal surface of the backing layer E in the central portion extends over the absorbent core 13 (Fig. 1), and the backing layer E defining a border portion extending beyond and surrounding peripheral edges of the absorbent core (Fig. 1), the distal surface of the backing layer defining the backside surface of the wound dressing. The backing layer carries a first skin adherent adhesive along the proximal surface of the border portion of the backing layer E and surrounding the peripheral edges of the absorbent core (Page 2, lines 61-63) A skin-adhering facing layer 11 is directly bonded to the proximal surface of the absorbent core 13, a proximal surface of the second facing layer 11 defining a portion of the bodyside surface of the wound dressing. A border portion of the backing layer is adjacent to and surrounds peripheral edges of the core inasmuch as the adhesion of the first facing layer to the skin holds the dressing together, which is interpreted herein as a tight seal around the core and second layer 11 such that they do not shift relative to one another. The facing layer 11 defines a grid pattern of through-extending apertures 20 arranged across the facing layer 11, with non-apertured regions surrounding the apertures. (Fig. 1, Page 1, lines 34-36, 47-51) The thickness of the non-apertured regions consists of the gel compound inasmuch as the facing layer 11 consists only of the gel compound. (Page 1, lines 64-79)

Steer discloses several skin adherent gel compounds including those using silicone as a binder, but does not explicitly disclose that the facing layer is a skin-adhering hydrophobic silicone-based facing layer. Lawry discloses a wound dressing having a second facing layer 16

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composed of a skin adherent hydrophobic silicone gel compound. ('410, ¶¶0037,0038) The article of Lawry seeks to solve a similar problem in the art to that with which applicant is concerned. Further, the silicone gel is equally or more capable of adhering to the skin compared to the hydrophilic gels disclosed by Steer because hydrophobic gels won't absorb sweat causing the gel to break down. Thus, it would be obvious to one of ordinary skill in the art to modify the article of Steer by replacing the water soluble hydrocolloid of the facing layer with a hydrophobic silicone-based material as disclosed by Lawry to ensure the second facing layer is still capable of adhering to the skin and will not absorb sweat, thus preventing breakdown of the layer during wear.

With respect to **claim 26**: Steer discloses that the entirety of the proximal surface of the backing layer E includes the skin adherent adhesive thereby extending across the central and border portions thereof. (Page 2, lines 55-61)

With respect to **claim 27**: The border portion of the backing layer E includes at least two opposed elongate sections, each opposed elongate section extending from a corresponding side of the absorbent core. (Fig. 2)

With respect to **claim 28**: The bodyside surface of the wound dressing necessarily consists of the skin adherent adhesive carried by the border portion of the backing layer E and the facing layer as they define the only surfaces that adhere to the skin when the bandage is in use to collectively define the bodyside surface of the dressing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761